K022417

12 Appendix F: 510(k) Summary

APR 10 2003

510(k) Summary

Submitter's Information:	Christian E. Hunt Care Rehab® 1124 Dominion Ct McLean, VA 22102 Phone: 1-703-448-9644 FAX: 1-703-356-2182.
Date of preparation:	July 23, 2002
Proprietary Name:	CARE STIM™
Common Name:	Muscle Stimulator
Classification Name:	Powered Muscle Stimulator 21 CFR 890.5850.
Device Classification:	Class II
Predicate Device:	Ortho Dx
Description of Device:	A portable NMS device for muscle re-education.
Intended Use:	The Classic Stim is recommended for use for the following conditions: • Relaxation of muscle spasms • Prevention or retardation of disuse atrophy • Increasing local blood circulation • Muscle re-education • Immediate post-surgical simulation of calf muscles to prevent venous thrombosis • Maintaining or increasing range of motion
Technological Comparison:	The CARE STIM™ has technological characteristics that are substantially equivalent to those of the predicate device, as determined by bench testing.
Labeling Comparison:	The labeling of the CARE STIM™ is substantially equivalent to that of the predicate device.
Nonclinical Testing:	Bench testing demonstrated that the output characteristics or CARE STIM™ are substantially equivalent to that of the predicate device.
Clinical Testing:	Not applicable.
Conclusions from Testing:	The CARE STIM™ is substantially equivalent in electrical output to the predicate device and any differences between the devices do not pose new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 0 2003

Mr. Christian E. Hunt
President
Care Rehab and Orthopaedic
1124 Dominion Court
McLean, Virginia 22102

Re: K022417
Trade Name: Care™ Stim
Regulation Number: 21 CFR 890.5380
Regulation Name: Powered Exercise Equipment
Regulatory Class: II
Product Code: GZJ
Dated: January 9, 2003
Received: January 13, 2003

Dear Mr. Hunt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use

510(k) Number: k022417

Device Name: CARE STIM™

Statement of Indication of Use:

The Classic Stim is recommended for use for the following conditions:

1. Relaxation of muscle spasms
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Muscle re-education
5. Immediate post-surgical simulation of calf muscles to prevent venous thrombosis
6. Maintaining or increasing range of motion

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE AS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022417